UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

RIDDHI USA, INC., and MOHD M. ALAM,

Defendants.

Civil Action No. 17-CV-6154
(Wexler, J.)
(Tomlinson, M.J.)

CONSENT DECREE OF PERMANENT INJUNCTION

WHEREAS, the United States of America, by its undersigned counsel, having commenced this action against Riddhi USA, Inc., and Mohd M. Alam ("Alam") (collectively, "Defendants"), by filing a complaint in this Court (the "Complaint"), a copy of which is annexed hereto as Exhibit A; and

WHEREAS, the parties wish to settle this action without further litigation and,

WHEREAS, Defendants having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree; NOW THEREFORE, it is hereby AGREED, ORDERED, ADJUDGED AND DECREED as follows that, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act") and the inherent power of this Court:

1. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332 and its inherent equitable authority, and has personal jurisdiction over all parties to this action.

2. The Complaint states a cause of action against Defendants under the Act.

3. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to

be introduced or delivered, into interstate commerce dietary supplements, as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of current good manufacturing practice regulations for dietary supplements ("Dietary Supplement cGMP"), as set forth in 21 C.F.R. Part 111.

4. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce dietary supplements, as defined by 21 U.S.C. § 321(ff), that are misbranded within the meaning of 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A) in that their labeling fails to declare information concerning their dietary properties, allergens, and ingredients, as well as the manufacturer's place of business.

5. Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and misbranded within the meaning of 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A).

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the equitable authority of this Court, from directly or indirectly manufacturing, preparing, processing, packing, labeling, holding, and/or distributing dietary supplements at or from 2231 5th Avenue, Suites 27 and 28, Ronkonkoma, New York 11779, or at or from any other location(s) at which Defendants now, or in the future, directly or indirectly manufacture,

prepare, process, pack, label, hold and/or distribute dietary supplements (the "facility"), unless and until:

A. Defendants' methods, facilities, processes, and controls used to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements are established, operated, and administered in compliance with this Decree, the Act, and its implementing regulations;

B. Defendants retain, at their expense, an independent person or persons (the "Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' facility to determine whether the facility, methods, processes, and controls are operated and administered in conformity with the cGMP regulations for Dietary Supplements, 21 C.F.R. Part 111. Defendants shall notify FDA in writing of the identity and qualifications of the Expert within five (5) calendar days after retaining the Expert;

C. The Expert performs a comprehensive inspection of the facility and the methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements to determine whether Defendants are in compliance with this Decree, the Act, and its implementing regulations;

D. The Expert certifies in writing to FDA that:

i. The Expert has inspected the facility and the methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements;

ii. All Dietary Supplement cGMP deviations brought to Defendants' attention by FDA, the Expert, or any other source have been corrected; and

iii. The facility, methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements are in compliance with this Decree, the Act, and its implementing regulations. The Expert's report of the inspection, which shall be submitted to FDA, shall include, but not be limited to, a determination that Defendants have methods, processes, and controls to ensure that they:

(1) Conduct at least one appropriate test to verify the identity of any component that is a dietary ingredient, as required by 21 C.F.R. § 111.75(a)(1)(i);

(2) Establish product specifications for identity, purity, strength, and composition of their finished dietary supplements, as required by 21 C.F.R. § 111.70(e);

(3) Verify that finished dietary supplements meet product specifications for identity, purity, strength, and composition, as required by 21 C.F.R. § 111.75(c);

(4) Establish and follow written procedures for quality control operations, as required by 21 C.F.R. § 111.103;

(5) Include all required elements of the master manufacturing records (MMRs), as required by 21 C.F.R. § 111.210;

(6) Establish complete batch production records, as required by 21 C.F.R. § 111.255(b); and

(7) Establish and follow written procedures for the requirements to review and investigate a product complaint, as required by 21 C.F.R. § 111.55

E. Defendants recall and destroy, under FDA's supervision, in accordance with the procedures provided in paragraph 7, all dietary supplements that were manufactured, prepared, processed, packaged, packed, labeled, held and/or distributed between December 22, 2015, and the date of entry of this Decree;

F. Defendants report to FDA, in writing, the actions they have taken to: (1) correct all of the Dietary Supplement cGMP deviations brought to Defendants' attention by FDA, the Expert, and any other source; and (2) ensure that the methods and processes used in, and the facilities and controls used for, manufacturing, preparing, packing, labeling, holding, and distributing dietary supplements are operated, and will be continuously administered in conformity with, Dietary Supplement cGMP;

G. FDA representatives inspect Defendants' facility to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with this Decree, the Act, and its implementing regulations;

H. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to paragraph 8, at the rates set forth in paragraph 14; and

I. FDA notifies Defendants, in writing, that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 6(A)-(F) and (H) of this Decree, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

7. Within fifteen (15) calendar days after entry of this Decree, Defendants, under FDA's supervision, shall destroy all dietary supplements that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and FDA's supervision. Defendants shall not dispose of any dietary supplements in a manner contrary to any federal, state, or local laws.

8. After Defendants have complied with paragraphs 6(A)-(F) and (H), and received FDA's written notification pursuant to paragraph 6(I), Defendants shall retain an independent person or persons (hereinafter, the "Auditor") who shall meet the criteria described in paragraph 6(B) to conduct audit inspections of Defendants' facility at least once every six (6) months for a period of no less than five (5) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to paragraph 6(I). If Defendants choose, the Auditor may be the same person or persons retained as the Expert described in paragraph 6(B). In addition, the following obligations apply to these audits:

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with Dietary Supplement cGMP and identifying any deviations

("Audit Report Observations"). As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) calendar days after the audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' facility and shall promptly make the Audit Reports available to FDA upon request.

B. If an Audit Report contains any observations indicating that Defendants are not in compliance with this Decree, the Act, and its implementing regulations, Defendants shall, within fifteen (15) calendar days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than fifteen (15) calendar days, Defendants shall, within five (5) calendar days after receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule. Within thirty (30) calendar days after Defendants receive an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule

approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) calendar days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

9. After receiving written notice from FDA as set out in paragraph 6(I), Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. Violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, dietary supplements, within the meaning of 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A);

B. Violates the Act, 21 U.S.C. § 331(k), by causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A);

C. Violates the Act, 21 U.S.C. §§ 331(d) and 350d, by failing to renew its food facility registration with FDA; or

D. Results in the failure to implement and continuously maintain the requirements of this Decree.

10. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report, or data prepared or submitted by Defendants, the Expert, the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any or all dietary supplements;

B. Recall, at Defendants' expense, any dietary supplements that in FDA's judgment is adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Institute or reimplement any of the requirements set forth in this Decree;

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to FDA.

11. Upon receipt of any order issued by FDA pursuant to paragraph 10, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 10 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Defendants shall pay all costs of all recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 10, at the rates specified in paragraph 14.

12. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to Defendants' places of business including, but not limited to all buildings, equipment, components, finished and unfinished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' components, finished and unfinished products, containers, packaging material, labeling, and other material; and examine and copy all

records relating to the receiving, manufacturing, preparing, packing, labeling, holding, and distribution of any and all of Defendants' products, including components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

13. Defendants shall promptly provide any information or records to FDA upon request regarding the receiving, manufacturing, preparing, processing, packing, labeling, holding, and distribution of Defendants' products.

14. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $93.26 per hour or fraction thereof per representative for inspection and investigative work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. Defendants shall make payment in full to FDA within twenty (20) calendars days after receiving written notification from FDA of the costs.

15. Within five (5) calendar days after entry of this Decree, Defendants shall post a copy of this Decree in a conspicuous location in a common area at Defendants' facility and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within ten

(10) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

16. Within ten (10) calendar days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. Within twenty (20) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, and list of attendees.

17. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, parties for whom Defendants contractually manufacture dietary supplements, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within twenty (20) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts.

18. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested) to such Associated Person(s). Within ten (10) calendar days of each time that any Defendant becomes associated

with any additional Associated Person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

19. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Riddhi USA, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

20. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: five thousand dollars ($5,000) in liquidated damages for each day such violation continues; an additional five thousand dollars ($5,000) in liquidated damages for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any distributed dietary supplements that are adulterated or otherwise in violation of this Decree, the Act, and/or its implementing regulations. Defendants understand and agree that the liquidated damages

specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

21. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

22. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

23. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence," sent by certified mail, and addressed to the District Director, New York District Office, United States Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433, and shall reference this civil action by case name and civil action number.

24. This Decree resolves only the claims in this statutory injunction action brought under 21 U.S.C. § 332(a) as set forth in the Complaint. Defendants specifically state and agree that entry of this Decree does not preclude any other civil, criminal, or administrative claims that

the government may have or may bring in the future against any of the Defendants herein in connection with, or relating to, any of the Defendants' activities involving FDA-regulated products, including the conduct alleged in the Complaint filed with this Decree.

25. Each party shall bear its own costs and attorney's fees, except as provided in Paragraphs 6, 11 and 14.

26. This Decree may be executed in separate counterparts, each of which constitutes an original and all of which constitute one and the same Decree. Signatures delivered by facsimile transmission, or as .pdf attachments to emails, shall constitute acceptable, binding signatures for purposes of this Decree.

27. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

The undersigned hereby consent to entry of the foregoing Decree.

FOR DEFENDANTS:

02/09/18
MOHD M. ALAM
on behalf of Riddhi USA, Inc.,
as its President and Owner

02/09/18
MOHD M. ALAM
in his individual capacity

PETER E. BRILL
Attorney for Defendants

FOR PLAINTIFF:

RICHARD P. DONOGHUE
United States Attorney
Eastern District of New York

2/28/18
EDWIN CORTES
Assistant United States Attorney

MONICA C. GROAT
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice, Civil Division
450 Fifth Street, NW, 6th Floor, South
Washington, DC 20001
Phone: 202-532-4218
Fax: 202-514-8742

OF COUNSEL:

ROBERT P. CHARROW
General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

ROSELLE N. OBERSTEIN
Associate Chief Counsel for Enforcement
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 209930002
Phone: 301-348-3011

The undersigned hereby consent to entry of the foregoing Decree.

FOR DEFENDANTS:

MOHD M. ALAM
on behalf of Riddhi USA, Inc.,
as its President and Owner

MOHD M. ALAM
in his individual capacity

PETER E. BRILL
Attorney for Defendants

FOR PLAINTIFF:

RICHARD P. DONOGHUE
United States Attorney
Eastern District of New York

EDWIN CORTES
Assistant United States Attorney

Monica C. Groat

MONICA C. GROAT
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice, Civil Division
450 Fifth Street, NW, 6th Floor, South
Washington, DC 20001
Phone: 202-532-4218
Fax: 202-514-8742

OF COUNSEL:

ROBERT P. CHARROW
General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

ROSELLE N. OBERSTEIN
Associate Chief Counsel for Enforcement
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-348-3011

SO ORDERED, this 27th day of March, 2018.

S/ Leonard D. Wexler

HONORABLE LEONARD D. WEXLER
UNITED STATES DISTRICT JUDGE